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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,647	10/17/2000	Andrew S. Greenberg	TUV-005.01	3460

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EXAMINER

SCHMIDT, MARY M

ART UNIT PAPER NUMBER

1635

DATE MAILED: 07/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/690,647		GREENBERG, ANDREW S.	
	Examiner		Art Unit	
	Mary Schmidt		1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1 and 3-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. In view of the Amendment filed 03/04/02 to claim 1, where the claim was amended from claiming administration of any MAPK pathway inhibitor to administration of ERK1/2, MEK or JNK inhibitors specifically, the following restriction requirement is now required for the reasons set forth below:

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1, 3-28, drawn to methods of using an ERK-1/2 inhibitor, classifiable in class 514, subclass 44.
 - II. Claims 1, 3-11 and 19-28, drawn to methods of using an MEK inhibitor, classifiable in class 514, subclass 44.
 - III. Claims 1, 3-11, 13-23 and 27-28, drawn to methods of using an JNK inhibitor, classifiable in class 514, subclass 44.
3. Inventions I, II and III are unrelated from each other since each is drawn to a method of preventing or treating a disease or conditions caused or contributed to by lipolysis of elevated FFA levels in a subject comprising administering an inhibitor of a different composition: ERK 1/2, MEK or JNK. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation since they are drawn to inhibiting different compositions that are

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structurally and functionally different: ERK ½, MEK, or JNK. Designing and/or using inhibitors to each of ERK ½, MEK, or JNK is considered a distinct invention because each ERK ½, MEK, or JNK is patentably distinct as per MPEP 803.04 which states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

Since the ERK ½, MEK, and JNK sequences (nucleic acid and protein) are structurally patentably distinct from each other, the inhibitors to each are patentably distinct, as well as methods of using inhibitors to each of the claimed sequences.

Furthermore, since the broad claim to any MAPK inhibitor as originally claimed has been amended to specifically claim the ERK ½, MEK or JNK target sequences, the issues for examination have changed to specifically target these sequences. As such, the enablement and art issues of the present claims are no longer all-encompassing of inhibitors of ERK ½, MEK or JNK along with any other MAPK inhibitor, and must be individually considered in more detail. The representative number of species of any inhibitor of any MAPK element versus a representative number of species individually for ERK ½, MEK or JNK inhibitors is substantially different in scope. Since the focus of the claimed invention has changed, the burden of

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examination has changed, and the instant restriction is now required for the scope of inhibitors of three very distinct target genes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and the search required for each of Group I, II and III is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt
July 23, 2002

A handwritten signature in cursive script, appearing to read "M. Schmidt", with a stylized flourish at the end.